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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,124	12/27/2005	Stanley R Terlecky	TERLECKY1A	5930
1444	7590	11/14/2008		
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER	
			PROUTY, REBECCA E	
			ART UNIT	PAPER NUMBER
			1652	
			MAIL DATE	DELIVERY MODE
			11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b> 10/533,124	<b>Applicant(s)</b> TERLECKY ET AL.
	<b>Examiner</b> Rebecca E. Prouty	<b>Art Unit</b> 1652

All participants (applicant, applicant's representative, PTO personnel):

(1) Rebecca E. Prouty.

(3) Stanley Terlecky.

(2) Samuel Livnat.

(4) Steven Hansen.

Date of Interview: 06 November 2008.

Type: a) Telephonic b) Video Conference  
c) Personal [copy given to: 1) applicant  
2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: All.

Identification of prior art discussed: All.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Rebecca E. Prouty/  
Primary Examiner, Art Unit 1652

## Summary of Record of Interview Requirements

### **Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### **Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  

(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed amendments to overcome the current 112, 2nd rejections Applicants proposed amending claim 2 to replace "further comprising" with "wherein the replacement sequence comprises" to clarify that the residues recited in claims 2-11 are part of the sequence which replaces the KANL sequence of human catalase and not the residues naturally amino terminal thereto. Examiner indicated that this would overcome the 112, 2nd rejection.

Discussed the current art rejections applicants argued that the disclosure of Sheik suggests that the KANL peptide must be retained and thus teaches away from the replacement thereof as claimed. Examiner indicated that while this argument might be applicable if Sheik is considered alone, the disclosure of Trelease clearly shows that replacement is also an option. Examiner indicated that the ordinary artisan would know that modifying a variety of consensus sequences to be more like the canonical consensus improves the function of the sequence, examples of which are found for promoters, Shine-Dalgarno sequences, signal sequences, etc.

Applicants referred to other portions of the cited references which they contend teach away from the claims, specifically, Sheik's teaching that Cat has a peroxisomal import pathway that is independent of either the PTS1 receptor or the PTS2 receptor. Because of this teaching, one of ordinary skill in the art would have had no motivation to modify the C-terminal sequence of Cat in any way other than the disclosed KANL-SKL. Applicant also stated that there would have been no reasonable expectation of success in modifying the C-terminal PTS1 sequence of Cat since Sheik concluded that a third pathway (for Cat import into peroxisomes) was involved. However, the examiner indicated that the suggestion of an additional peroxisome import pathway of catalase in no way teaches away from modifying the catalase to include a PTS1 targeting signal to improve its import by the PTS1 pathway.

Applicants highlighted portions of Trelease that also teach away, particularly the statement "the C-terminal tripeptide ANL-COOH was necessary and sufficient for peroxisome targeting." Examiner noted that Trelease showed that rat Cat-KSHL was targeted to the peroxisome and thus ANL can clearly be replaced by other peroxisomal targeting sequences. However, Applicants stated that nothing in Trelease suggests that Cat import would be improved by substituting SHL for ANL, only that both sequences could deliver Cat to the peroxisome to some extent. However, examiner indicated that an ordinary skilled artisan's expectation would be that the more canonical SHL sequence would be better. Applicants further distinguished the present invention over Trelease and the other cited art in that the application teaches the superiority of the claimed replacement peptides to the native a C-terminal KANL sequence in delivering Cat to peroxisomes.

Applicant stated that the teachings of Fujiwara would not have provided any reasonable expectation of success in seeking to improve Cat import by modifying its native C-terminal sequence. Particularly relevant was Fujiwara's conclusion that in mutant cells associated with peroxisome biogenesis disorders, restoration of Cat import depends on transitioning the mutant Pex2p (docking protein) gene from an inactive state to an active state. Hence, modifying the native Cat C-terminal sequence would not have been expected to restore Cat import to the mutant cells. However, examiner indicated that Fujiwara's indication that other peroxisomal proteins with standard PTS1 targeting sequences do get imported does in fact suggest that the defect is caused by the combination of a defective receptor with the non-standard targeting sequence of catalase.

Examiner indicated that while she wasn't likely to find applicants arguments regarding teaching away convincing in this case, that submission of a declaration showing unexpected results for specific replacement of the natural sequence and/or for sequences including specific additional residues might be persuasive. Examiner would need to see the showing before making any decision regarding such evidence